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| 10/586,331 | 01/04/2007 | Shoji Takeuchi | 293407US0PCT | 1830 |
| 22850 7590 01/07/2011 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314 | | | | |
| EXAMINER | | | | |
| ZISKA, SUZANNE E | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1619 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/586,331

Applicant(s)

TAKEUCHI ET AL.

Examiner

SUZANNE ZISKA

Art Unit

1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

Claims 1-20 are pending in this application.

Status of Rejections

1. The rejection of claims 1-19 under 35 USC 103 as being unpatentable over Vogel et al (US 2003/0146091) is maintained for reasons of record.

Applicants' arguments filed 10/25/10 have been considered but not found persuasive.

Applicants argue that Vogel does not disclose or suggest forming a planar lipid-bilayer membrane by adding a buffer solution after addition of lipid solution. However, Vogel discloses [0270] that a very small fluid volume can be used for fast attachment and the fluid volume can be increased immediately thereafter, suggesting addition of a buffer solution from the upper side after adding the lipid (in this case a cell).

Applicants argue that Vogel neither discloses nor suggests forming a lipid-bilayer membrane from a solution comprising no microstructure in the form of a liposome or lipid bilayer. However, Vogel discloses that membrane proteins can be analyzed [0250], thus disclosing forming lipid bilayers comprising membrane proteins which meets the claim element of "no microstructure in the form of a liposome or lipid bilayer."

Applicants argue that Vogel does not include a liquid trap. However, Vogel discloses that one of the fluid compartments [0071]-[0073] can, in addition to covering the sample, be open or closed. Vogel discloses that closed compartments are physically confined and are established within voids and channels therein [0073]. The void and channels appear to be the same as the claimed "liquid trap," lacking evidence to the contrary.

Applicants argue that Vogel does not teach a microinjection device. However, Vogel discloses that features selected from standard microplates can be used. A microinjection device is a feature used in conjunction with microplates.

Applicants argue that Vogel does not teach a channel within a partition wall. However, Vogel discloses that closed compartments are physically confined and are established within voids and channels therein [0073]. The voids and channels appear to be the same as the claimed "liquid trap" lacking evidence to the contrary.

Applicants argue that Vogel does not teach a tapered aperture. However, Vogel discloses that the aperture is substantially tapered in a "first" layer and cylindrical in the "second" layer. Applicants' device shown in figure 8f, for example, has the same structure (cylindrical and tapered).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 2, 4, 5, 9-13, 17 and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by Suzuki et al ("Planar Lipid Membrane Array for Membrane Protein Chip," 17th IEEE International Conference of Microelectro Mechanical Systems, pages 272-275, Maastricht MEMS 2004 Technical Digest, January 25-29, 2004).

Suzuki discloses a method of forming a planar lipid-bilayer membrane for membrane protein analysis [title], by filling a microchannel with a buffer solution wherein the microchannel is under a horizontal partition wall having an aperture, applying a lipid solution to the aperture filled with the buffer solution to form a thin lipid layer in a chamber having a liquid trap on the partition wall on the inside of the chamber and application of the buffer solution as a droplet to the chamber from the upper side. See, for example, figures 3, 5, 6, 9 and 10 (claim 1).

Regarding claim 2, Suzuki discloses the excess of lipid solution flows into the trench to make the lipid layer on the aperture thin enough (page 273, right column, third full paragraph), thus disclosing the thin layer of the lipid solution is controlled.

Regarding claims 4 and 5, Suzuki discloses a plurality of chambers (figure 8) in an array, thus disclosing a plurality of chambers integrally formed.

Suzuki discloses a device (figure 10) having a substrate, a partition wall over the substrate, a microchannel, a chamber having an aperture formed in the wall and a liquid trap, a lower channel filled with a buffer and a microinjection device for applying droplets of a lipid solution and a buffer solution to the chamber from the upper side of the chamber. See, figures 9 and 10. The device in Figure 9C appears to be identical to Applicants' device as shown in specification figure 2C (claim 9).

Regarding claim 10, electrodes are shown near the liquid trap and near the substrate (figures 5, 6 and 10A).

Regarding claim 11, Suzuki discloses a channel connected to the liquid trap for controlling the thickness of the layer (page 273, right column, 4th full paragraph and figure 6 iv).

Regarding claims 12 and 13, Suzuki discloses a plurality of chambers (figure 8) in an array, thus disclosing a plurality of chambers integrally formed.

Regarding claim 17, an aperture having a narrowing from the lower side to the upper side is shown in figure 5.

Regarding claim 18, figure 3 shows a silicon substrate and that the aperture was etched.

Claim Rejections - 35 USC § 112

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 20 requires a lipid solution which comprises no microstructure in the form of a liposome or lipid bilayer.

The specification discloses addition of a lipid solution (for example, page 6, line 9) and specifically discloses addition of liposomes (for example, page 6, lines 17-23). The specification fails to disclose that the lipid solution which is added has no

microstructure in the form of a liposome or lipid bilayer. The specification fails to disclose methods by which the nature of the lipid solution may be determined such that a lipid solution having no microstructure in the form of a liposome or lipid bilayer can be identified or that such a solution was added. Because there is no suggestion in the specification to use a lipid solution having no microstructure or methods/guidance for identifying a lipid solution having no microstructure, one of ordinary skill in the relevant art would not be aware that a lipid solution having no microstructure was part of Applicants' disclosed invention. Applicants' identified support for the amendment and assertion that "no new matter has been added" is not persuasive.

Applicants state on page 7 of the amendment that figure 3A supports the phrase "the lipid solution comprises no microstructure in the form of a liposome or lipid bilayer." However, the specification discloses that figure 3A merely represents a component (phospholipid) having a hydrophilic groups 20A and a hydrophobic group 20B and is silent on the nature of any structures which are or are not formed.

Therefore, claim 20 fails to comply with the written description requirement.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUZANNE ZISKA whose telephone number is (571)272-8997. The examiner can normally be reached on Monday through Friday 9 AM to 5 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Z./
Examiner, Art Unit 1619